

July 30, 2002

Walter L. Jones
Pine Chemicals Association, Inc.
1117 Perimeter Center West
Suite 500E
Atlanta, Georgia 30338

Dear Mr. Jones:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for the Fatty Acid Dimers and Trimer category, posted on the ChemRTK Web Site on April 4, 2002. I commend the Pine Chemicals Association, Inc. for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed Comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the Pine Chemicals Association, Inc. advise the Agency, within 90 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

**EPA Comments on Chemical RTK HPV Challenge Submission:
Fatty Acid Dimers and Trimer Category**

SUMMARY OF EPA COMMENTS

The sponsor, the Pine Chemicals Association, Inc., submitted a test plan and robust summaries to EPA for the Fatty Acid Dimers and Trimer category dated March 15, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on April 4, 2002.

EPA has reviewed this submission and has reached the following conclusions:

1. Category Justification. The submitter's support for grouping the chemicals under this category is acceptable.
2. Physicochemical and Environmental Fate Data. (a) EPA agrees with the submitter's proposal to provide measured values for water solubility, partition coefficient, and biodegradation. (b) EPA agrees that a stability in water test is not necessary. (c) EPA believes that the other endpoints can be measured/estimated for representative substances and thus the fugacity model can be run.
3. Health Effects. EPA agrees that the adequate existing data and the proposed reproductive/developmental screening test (OECD TG 421) on dimer, can be reasonably extrapolated to the other category members.
4. Ecological Effects. EPA agrees with the submitter's proposal to conduct acute fish, daphnia, and algal tests on dimer, which can be reasonably extrapolated to the other category members. However, EPA has specific comments on how the tests should be conducted.

EPA requests that the submitter advise the Agency within 90 days of any modifications to its submission.

**EPA COMMENTS ON THE FATTY ACID DIMERS AND TRIMER CATEGORY CHALLENGE
SUBMISSION**

Category Definition

The submitter has proposed a category covering fatty acid dimers and trimer. All the members of the category are produced by the dimerization of C18 unsaturated fatty acids, primarily tall oil fatty acids. Members of the category are liquids, ranging from colorless to dark brown. The viscosity of the members depends on the dimer and trimer content, with crude dimer being a low viscosity liquid and at the other extreme, trimer being a very viscous liquid. Dimers and trimer are predominantly cyclic addition compounds of unsaturated fatty acids, although bicyclic, non-cyclic and other structures are present. The category members are: fatty acids, C18-unsaturated, dimers (dimer) (CAS No. 61788-89-4); fatty acids, C18-unsaturated, trimers (trimer) (CAS No. 68937-90-6); fatty acids, C18-unsaturated, dimers, hydrogenated (hydrogenated dimer) (CAS No. 68783-41-5); and fatty acids, C16 and C18-unsaturated, dimerized (crude dimer) (CAS No. 71808-39-4). The category definition is clear and unambiguous.

Category Justification

The submitter bases the category on similar chemical composition. The members of the category are all mixtures of monomer, dimer and trimer. The submitter states, "Since all the substances in the category are either dimers or trimers of fatty acids, they are in the same family of compounds. Thus, these substances meet EPA's criterion of using the "family approach" to group chemicals into a category to

examine related chemicals.” The submitter indicates that dimer (the distilled form) will be used for the ecotoxicity and developmental toxicity testing because it is the most commercially important substance, with the largest production volume, and has the highest dimer content of the category members so the results will be most representative of the category. Although adequate test data are only available for dimer, EPA believes that because of the chemical similarities of the four substances, the existing and proposed testing can be reasonably extrapolated to the other category members.

Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

Water solubility and partition coefficients will be determined for all category members. However, the submitter has proposed not determining melting point, boiling point, and vapor pressure because of the physical characteristics of the substances. EPA disagrees, and believes that the submitter can get measured/estimated values for these endpoints for representative substances.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

Adequate biodegradation data are available for dimer, and the submitter proposes to generate biodegradation data on the other three members of the category. EPA agrees that stability in water need not be determined because the substances contain no hydrolyzable groups. The submitter has proposed not determining photodegradation or running the fugacity model due to the lack of usable inputs to the model. As above, EPA believes that measured/estimated values can be determined thus providing inputs to the fugacity model.

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Adequate test data are available for the acute, genetic, repeat dose, and reproductive toxicity endpoints for dimer. The submitter proposes to conduct a reproductive/developmental toxicity screening test (OECD TG 421) to address these endpoints. The results from the existing data and the proposed developmental toxicity test will be extrapolated to the other three category members. EPA agrees with this approach. HPV Challenge Program guidance indicates that when a study addresses multiple endpoints, robust summaries are needed for each endpoint. Therefore, the submitter needs to include a robust summary for the reproductive toxicity endpoint, i.e., evaluation of reproductive organs from the repeated-dose toxicity study.

Ecotoxicity (fish, invertebrates, and algae). The submitter proposes to conduct acute fish, daphnid, and algae tests on dimer and extrapolate the results to the other three category members. EPA does not agree on how the tests should be conducted. EPA believes these chemicals have an inherent tendency to form an aqueous milky dispersion, emulsion, or critical micelles. The soluble salts of these chemicals should be dispersible in water just as surfactants and detergents are dispersible in water. In this case, when testing, the overall test substance concentrations should not exceed the dispersibility limit or the critical micelle concentration. The test substance solubility should not be viewed as a water solubility limit. EPA recommends that these tests be done at pH 7, instead of the proposal of reducing the pH in these tests. EPA disagrees with using filters, centrifugation, or water-accommodated fractions to separate any of the test substance, but rather believes that the chemical as manufactured should be tested. If conducted according to this guidance, there should not be any physical toxicity.

Followup Activity

EPA requests that the submitter advise the Agency within 90 days of any modifications to its submission.